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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/901,181

07/09/2001

J. Lawrence Burg

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MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER

KIM, YOUNG J

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

05/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/901,181

Applicant(s)

BURG ET AL.

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Upon careful updated search of the prior art prior to allowance, at least one reference was deemed to be pertinent and applicable to at least one pending independent claim(s).

Therefore, the finality of the last Office Action is hereby withdrawn, and prosecution, reopened for the application of the following rejections.

Ms. Lisa Hillman was advised that the prosecution would be reopened during a telephonic conversation that took place on May 8, 2007.

Preliminary Remark

Claims 10-36 are pending and are under prosecution herein.

Double Patenting

The rejection of claims 10, 14-16, and 21-24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of the U.S. Patent No. 6,300,068 made in the Office Action mailed on May 9, 2006 is withdrawn in view of the Terminal Disclaimer which was received on April 27, 2007.

The rejection of claims 11-13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of the U.S. Patent No. 6,300,068 in view of Backus et al. (U.S. Patent No. 6,280,930), made in the Office Action mailed on October 13, 2005 is withdrawn in view of the Terminal Disclaimer which was received on April 27, 2007

The rejection of claims 11 and 17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of the U.S. Patent No. 6,300,068 in view of Backus et al. (U.S. Patent No. 6,280,930) and Harris et al. (U.S. Patent No. 5,849,544) made in the

Office Action mailed on October 13, 2005 is withdrawn in view of the Terminal Disclaimer which was received on April 27, 2007.

The rejection of claims 19-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of the U.S. Patent No. 6,300,068 in view of Collins et al. (U.S. Patent No. 6,268,128) made in the Office Action mailed on October 13, 2005 is withdrawn in view of the Terminal Disclaimer which was received on April 27, 2007.

The rejection of claims 27-36 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,300,068, made in the Office Action mailed on October 13, 2005 is withdrawn in view of the Terminal Disclaimer which was received on April 27, 2007.

Rejection, New Grounds

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10, 14-16, and 21-24 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-16 of U.S. Patent No. 5,786,182 (IDS ref, herein, '182 patent).

Claim 14 of '182 patent is drawn to a method of isothermal (column 6, line 53) amplification, wherein the claim employs a dual chamber apparatus, wherein said dual chambers are in fluid communication with each other, said method comprising the steps of:

- a) loading an amplification reagent(s) into the first chamber of said dual chamber and an amplification enzyme in the second chamber of said dual chamber;
- b) heating said first chamber and said sample to a first relatively high temperature (which would necessarily denature any double stranded nucleic acids and render single-stranded nucleic acids maintain their single-strandedness);
- c) cooling said first chamber and a solution of said sample and amplification reagents from said first relatively high temperature (which would result in the annealing of primers);
- d) passing the solution said first chamber (which contains the sample and the amplification reagents) into the second chamber which contains said amplification enzyme, thereby resulting in their contact to provide a nucleic acid amplification mixture;
- e) amplifying said solution in said second chamber by said amplification enzyme.

While claim 14 of '182 patent does not explicitly recite an explicit step of detecting the amplified product, such step is well known and practiced in the art, and would have been obvious to one of ordinary skill in the art since one would desire to detect whether the target was present or not when amplifying a target nucleic acid sequence (see also column 3, lines 28-34 of '182 patent), rendering instant claims 10, 15, 27, 29, and 31 obvious.

With regard to instant claims 14 and 30, claim 14 of '182 patent generically recites the term, amplification reagent(s), but it should be clear that amplification cannot proceed without the presence of nucleotide triphosphates, primers, and in some form of a buffer. In addition, column 6, beginning at line 23, the specification of '182 patent evidences this fact:

“Chamber A contains the amplification reagents or mix, namely deoxynucleotides, primers, $MgCl_2$, and other salts and buffer components”

With regard to instant claims 16 and 34, claim 16 of '182 patent recites that the amplification enzyme from the second chamber of said dual chamber is brought into contact to the sample in the first chamber of said dual chamber (see 6th step).

With regard to claims 17-19, the detection is achieved by SPR, which is disclosed as being a pipette-like device (column 3, line 29-30), which is employed for the detection via hybridization, washing, and optical analysis (column 3, lines 31-32).

With regard to claims 12-13 and 20, '182 patent explicitly disclose that detection via use of SPR can be conducted, “in accordance with well known techniques.” (column 3, lines 31-34)

Clearly, the steps of washing the probe-bound analytes prior to their detection so as to remove non-specific hybridization signals, wherein signals are generated from labeled probes, have been well known and employed in the art of nucleic acids hybridization/detection.

With regard to claims 22 and 33, the amplification enzyme is disclosed as being in the form of a pellet (column 10, line 6).

With regard to claim 23, the second reaction chamber is sealed prior to use (see claim 14 of '182 patent).

With regard to claims 24-26, 35, and 36, the device employed by '182 patent employs a thimble valve (column 10, line 53).

With regard to claims 21 and 32, '182 patent is drawn to the automated analysis of the sample without the need for human intervention (Abstract), and employs systems such as VIDAS, which would necessarily employ the requisite detectors and analyzers.

Therefore, the invention as claimed is obvious over claims 14-16 of '182 patent.

Conclusion

No claims are allowed.

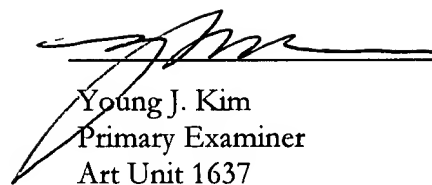
Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Art Unit: 1637

A handwritten signature in black ink, appearing to read 'Young J. Kim', is written over a horizontal line.

Young J. Kim

Primary Examiner

Art Unit 1637

5/9/2007

**YOUNG J. KIM
PRIMARY EXAMINER**

YJK